

Remarks

This paper is responsive to the Final Office Action mailed December 10, 2007 and Advisory Action mailed May 6, 2008.

Claims 4, 6-8, 15, and 26-27 are pending. In the Actions, the Office rejected the claims under 35 U.S.C. § 112, first paragraph. Applicant hereby amends claim 4, cancels claim 6, and respectfully requests reconsideration of the claims.

Claim Rejection – 35 U.S.C. § 112, first paragraph

The Office has rejected the claims under 35 U.S.C. § 112, first paragraph, because the specification fails to provide enablement for the full scope of the claimed invention. The Office has stated that claim 4 fails to recite that the KChAP nucleic acid is operably linked to a promoter active in the cancer cells, but that such language is present in dependent claim 6. Applicant has amended claim 4 to include the language of claim 6, and canceled claim 6. Applicant respectfully requests withdrawal of the rejection of claim 4.

The Office has further asserted that the evidence of record as a whole indicates that the heterotopic subcutaneous xenotransplantation of cell lines in an immunodeficient mouse fails to reflect human carcinoma and that systemic delivery and expression of KChAP nucleic acid is unpredictable. In light of this assertion the Office claims that a person of ordinary skill in the art would need to carry out undue experimentation to determine whether a systemic delivery method using any type of expression vector encoding KChAP in a heterotopic tumor model using cell lines would be effective in inducing apoptosis in human epithelial carcinoma *in vivo* or treating a subject with prostate cancer. Applicant respectfully traverses this rejection.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, is it undue. Furthermore, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. M.P.E.P. § 2164.01. Applicant respectfully points out that the *Wands* factors analyzed by the Office actually may argue in favor of enablement. The instant specification provides multiple working examples and very detailed and specific guidance, including KChAP overexpression in

prostate cancer cells (example 1), inducing apoptosis in prostate cancer cells (example 2), inhibiting *in vivo* growth of subcutaneous implants of human prostate cancer cells (example 3), inducing apoptosis in breast cancer cells (example 4), and detection of cancer cells with anti-KChAP antibodies (example 5). This disclosure puts one of ordinary skill in the art in a position to readily understand the full scope of the claimed invention and would only require routine, if potentially complex, experimentation to arrive at the full scope of the claimed invention. Applicant has provided sufficient guidance to enable one of ordinary skill to appreciate the full scope of the claimed invention. Even if the experiments are numerous and complex, they are not undue as they would be routine to practice the full scope of the claimed invention. Applicant has provided all the necessary steps to practice the claimed method of inducing apoptosis and has even disclosed in example 5 a method of detecting the presence of any cancer cells to determine the efficacy of the claimed method. One of ordinary skill in the art would have no difficulty in practicing the claimed invention on human epithelial carcinoma or treating a subject with prostate or breast cancer, as the claimed steps of delivering and expressing KChAP via a viral vector in a tumor in a subject by intratumoral injection would require no more the routine experimentation. Applicant respectfully submits that the claims as amended are enabled and requests withdrawal of the rejection.

In the event the Commissioner should decide that any additional fee or fee deficiency is due, the Commissioner is hereby authorized to charge any and all fees incurred as a result of entering or considering this document to deposit account number 03-0172.

Respectfully submitted,

Calfee, Halter & Griswold LLP

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By: /milan jovanovic/
Milan Jovanovic
Reg. No. 60,798
(614) 621-7768
(614) 621-0010 (fax)
mjovanovic@calfee.com